IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL No. 2875 (RBK/KW)
This Document Relates To All Actions.	:	**MTD OPINION 4**

KUGLER, United States District Judge:

Before this Court are defendants' Motions to Dismiss (Doc. No. 520, 522, 523) the three Master Complaints[1] filed in this Multi-District Litigation ["MDL"], which involves the sale of a generic blood pressure medication found to be contaminated with probable human carcinogens. Because the MTDs seek dismissal of several claims for each set of plaintiffs, the Court is issuing a series of opinions to resolve the motions. Each opinion will be numbered with this opinion being the fourth in the series.

This OPINION 4 resolves defendants' arguments relating to Rule 12(b)(6) pleading deficiencies. An ORDER 4 of this date accompanies this OPINION 4.

The COURT HAVING REVIEWED the parties' submissions (without a hearing in accordance with Rule 78.1 (b)) relating to the fraud-based claims, including negligent misrepresentation, and on the strict liability claims for failure to warn and for design defect, and for the reasons stated below, and for good cause shown:

As for the Fraud–based Claims:

Against the Manufacturing Defendants:

The Court **DENIES** the Manufacturing Defendants' motion to dismiss the **fraud-based claims (fraudulent misrepresentation; fraudulent concealment; fraud by omission; state consumer protection statute claims that sound in fraud) as well as the negligent misrepresentation claims, in the ELMC, the PIMC, and the MMMC.**.

Against the Wholesaler Defendants and the Pharmacy Defendants:

The Court **GRANTS** the Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the **fraud-based claims (fraudulent misrepresentation; fraudulent concealment; fraud by omission; state consumer protection statute claims that sound in fraud) in the ELMC, the PIMC, and the MMMC and dismisses these claims WITHOUT PREJUDICE**.

[1] the Economic Loss Master Complaint ["ELMC"] (ECF Doc. 121); the Personal Injury Master Complaint ["PIMC"] (ECF Doc. 122); and the Medical Monitoring Master Complaint ["MMMC"] (ECF Doc. 123)

Plaintiffs may file a motion for LEAVE TO AMEND these Master Complaints as to the fraud-based claims against the Pharmacy Defendants and the Wholesaler Defendants, according to the deadline set forth in the accompanying Order.

As for the Negligent Misrepresentation Claims:

Against the Wholesaler Defendants and the Pharmacy Defendants:

The Court **GRANTS** the Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the negligent misrepresentation claims in the **in the ELMC, the PIMC, and the MMMC and dismisses these claims WITHOUT PREJUDICE**.

Plaintiffs may file a motion for LEAVE TO AMEND these Master Complaints as to the negligent misrepresentation claims against the Pharmacy Defendants and the Wholesaler Defendants, according to the deadline set forth in the accompanying Order.

As for Strict Liability-Design Defect Claims Relating to Manufacturing Defect:

Against the Manufacturing Defendants in the PIMC

The Court **GRANTS** the Manufacturing Defendants' motion to dismiss the **strict liability-manufacturing defect claim in the PIMC that arise under the laws of Delaware, Massachusetts, North Carolina, Virginia, Indiana, and Pennsylvania** and **dismisses these claims WITH PREJUDICE.**

As for Strict Liability-Design Defect Claims NOT Relating to Manufacturing Defect:

The Court **DENIES** the Manufacturing Defendants' motion to dismiss the **strict liability-design defect claims in the PIMC** that arise under the **laws of states that do NOT prohibit strict liability- design defect claims**.

As For Strict Liability- Failure To Warn Claims in the PIMC and MMMC

Against Manufacturing Defendants

The Court **DENIES** the Manufacturing Defendants' motion to dismiss the **strict liability-failure to warn claims in the PIMC and the MMMC** that arise **under the laws of states that do NOT prohibit strict liability failure to warn claims.**

The Court **GRANTS** the Manufacturing Defendants' motion to dismiss the **strict liability-failure to warn claims in the PIMC and the MMMC** that arise **under the laws of states that PROHIBIT strict liability failure to warn claims.**

Against Wholesaler and Pharmacy Defendants

The Court **DENIES** the **Wholesaler Defendants' and the Pharmacy Defendants' motions to dismiss the strict liability-failure to warn claims in the PIMC and the MMMC.**

These defendants , at a later, appropriate stage of these proceedings, may raise this issue with the Court by way of a motion for summary judgment.

1.0 BACKGROUND

Millions of Americans suffer from high blood pressure. Two common medications used to treat this condition are Diovan and Diovan HCT and Exforge and Exforge HCT. This case involves their generic counterparts, Valsartan and its combination therapy with hydrochlorothiazide and Amlodipine-valsartan and its combination therapy with hydrochlorothiazide (collectively the valsartan-containing drugs or "VCDs"). While generic drugs are supposed to be bioequivalent to their brand-name counterparts, at some point these VCDs were found to be contaminated with probable human carcinogens known as N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). This led to a recall of the VCDs in July of 2018. The current lawsuits stem from defendants' manufacturing, promotion, and sale of the VCDs and their subsequent recall. Plaintiffs, consumers and Third-Party Payors ["TPP"] who purchased or made reimbursements for defendants' contaminated VCDs, brought an economic damage and a medical monitoring class action against Defendants. They also brought a personal injury action against defendants, which are entities with various and sometimes overlapping roles within the supply chain. They include the manufacturers ("Manufacturing Defendants") of the drug (both the manufacturers of the active pharmaceutical ingredient and the manufacturers that make the finished drug product), the wholesalers ("Wholesaler Defendants") who obtain the finished drug product and resell it to retailers, and consumer-level distributors ("Pharmacy Defendants"). Because the mechanics of the pharmaceutical supply chain are more important for this motion, we will briefly provide an overview of how it works and each defendants' role in it.

1.1 Pharmaceutical Supply Chain

Generally, there are four actors in the pharmaceutical supply chain: (1) the manufacturers; (2) wholesaler distributors; (3) pharmacies; and (4) pharmacy benefit managers.[2] The manufacturers consist of both the active pharmaceutical ingredient ("API") manufacturers and the finished-dose manufacturers. The API manufacturers create the pharmaceutical ingredient in the medication that is used to produce the intended pharmacological effect. Often, the API manufacturers are part of a company's vertically integrated supply chain, meaning one company operates at both the

[2] The Pharmacy Benefit Managers are not relevant for purposes of this motion.

manufacturer and wholesaler/distributor level. However, on occasion, pharmaceutical companies will contract with other companies to manufacture the API instead of manufacturing it themselves. Here, these companies are referred to as the finished-dose manufacturers. The manufacturers, either the finished dose or API manufacturers, then distribute the drugs to wholesalers, who in turn redistribute the drug to pharmacies for sale to the public.

In this case, the active pharmaceutical ingredient manufacturers were: (1) Zhejiang Huahai Pharmaceutical Co., Ltd—the parent company for Huahai US Inc., Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC, and Solco Healthcare US, LLC (collectively known as "ZHP defendants"); (2) Hetero Drugs, Limited—the parent company for Hetero Labs, Ltd., Hetero USA Inc., and Camber Pharmaceuticals, Inc. (collectively known as "Hetero defendants"); (3) Mylan N.V.—the parent company for Mylan Laboratories, Ltd. and Mylan Pharmaceuticals, Inc. (collectively known as "Mylan defendants"); and (4) Aurobindo Pharma, Ltd.—the parent company for Aurobindo Pharma USA, Inc. and Aurolife Pharma, LLC (collectively known as "Aurobindo defendants"). These API manufacturers also acted as finished-dose manufacturers.

The finished-dose manufacturers were: (1) Teva Pharmaceutical Industries Ltd.—the parent company for Teva Pharmaceuticals USA, Inc., Arrow Pharm Malta Ltd., Actavis Pharma, Inc., and Actavis, LLC (collectively known as "Teva Defendants"); and (2) Torrent Private Limited—the parent company for Torrent Pharmaceuticals, Ltd., and Torrent Pharma, Inc. (collectively known as "Torrent defendants").

The ZHP defendants manufactured the valsartan-containing API for Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., and Torrent Pharmaceuticals, Ltd. Similarly, the Mylan defendants manufactured some of the valsartan-containing API for Teva Pharmaceuticals USA, Inc.

The finished-dose manufacturers then distributed their VCDs to the wholesalers, which included Cardinal Health, McKesson Corporation, and AmerisourceBergen Corporation. These wholesalers, in turn, redistributed the VCDs to the retail pharmacies for final distribution to the general public. The pharmacies included CVS Health, Walgreens Boots Alliance, Inc., Express Scripts, Inc., OptumRx, Walmart, Inc., the Kroger Co., Rite Aid Corp., Albertsons Companies, LLC., and Humana Pharmacy, Inc.

1.2 Factual Background

In the wake of the success of the blood pressure medications DIOVAN and EXFORGE, many generic drug manufacturers sought to capitalize on this success by introducing their own generic versions of the Valsartan drug. Doc. No. 398, Am. ELMC ¶¶ 217–20. They filed Abbreviated New Drug Applications ("ANDA") with the FDA and waited for Novartis' patents for DIOVAN and EXFORGE to

expire so that they could enter the market. *Id.* ¶ 219. Upon approval of their ANDAs, the Manufacturing Defendants sought and received inclusion of their VCDs in the Orange Book—an FDA approved list of drugs that are considered to be both effective and safe. *Id.* ¶ 361. Inclusion in the Orange Book imposed a continuing obligation on the Manufactuing Defendants to demonstrate that the VCDs were therapeutically equivalent to their brand-name counterparts. *Id.* ¶ 362. In 2012 and the years following, generic versions of the Valsartan drug, which were affixed with FDA approved labels, inundated the U.S. market. *Id.* ¶ 363.

Both the API and finished-dose manufacturers held themselves out as being regulatorily compliant and providing generic drugs that were as safe and efficacious as the brand-name counterparts. Specifically, on their websites and in marketing materials, the finished-dose and API manufacturers represented that their VCDs were cGMP compliant and bioequivalent to the brand-name counterparts. *Id.* ¶ 365). For instance, on ZHP's website, it represented that it "ha[d] established an independent, strict and sound quality mangement [sic] system in accordance with GMP" and "ensure[d] that production is operated in accordance with GMP." *Id.* ¶ 376. Prinston and Solco both represented that their valsartan was equivalent to Diovan. *Id.* ¶ 378, 381. Likewise, Hetero's much touted state-of-the-art manufacturing facilities were represented as "cGMP compliant" and "approved by various Ministries of Health and regulatory authorities like US FDA." *Id.* ¶ 383. Hetero also describes its generic drugs as:

> copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity, and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs.

Id. ¶ 385. Camber followed suit by comparing its valsartan to Diovan on its website. *Id.* ¶ 386. Mylan's representations were no different. Its website claimed that "[g]eneric pharmaceuticals are the same as existing approved brand-name drugs in active ingredient, dosage form, safety, strength, route of administration, quality and performance characteristics" and assures consumers that "FDA-approved generic products have [met] the same rigid manufacturing standards as the innovator drug." *Id.* ¶ 387–88. Similarly, Torrent's website stated it "strongly believe[s] in providing quality medicines at affordable price to the patients" and to do so it safeguards "both the qualitative and quantitative aspects with the help of [its] robust manufacturing technologies and manufacturing facilities." *Id.* ¶ 392. Aurobindo referred to valsartan as "the generic equivalent to the reference listed drug product (RLD) Diovan®" and described itself as [c]ommitted to [q]uality and [s]afety." *Id.* ¶ 393–94. Likewise, Aurolife described its

manufacturing facility as "state-of-the-art US FDA approved cGMP compliant." *Id.* ¶ 397. Lastly, Teva "guarantee[s] the quality of [its] products" through "impeccable adherence to . . . cGMPs"[3] and it, along with Actavis, Teva USA, Arrow, and Actavis Pharma, stated their VCDs were bioequivalent to reference listed drugs. *Id.* ¶ 400, 403.

Despite these representations, the FDA uncovered numerous violations of cGMPS upon inspection of the manufacturers' foreign manufacturing facilities. After an inspection in 2016, the FDA found that "[w]ritten procedures designed to prevent contamination of drug products purporting to be sterile [were] not followed" and that ZHP had failed "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." *Id.* ¶ 239. A May 2017 inspection revealed "that ZHP repeatedly re-tested out of specification . . . samples until obtaining a desirable result" and that "impurities occurring during analytical testing [were] not consistently documented/quantitated." *Id.* ¶ 240. Ultimately, the FDA issued a warning letter to ZHP and explained that ZHP failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." Specifically, ZHP:

> approved a [V]alsartan API process change . . . that included the use of the solvent. [ZHP's] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities [, such as NDMA,] when [it] implemented the new process. . . . [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted]. According to [ZHP's] ongoing investigation, [redacted] is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process.

Id. ¶ 246. ZHP claimed it had followed common industry practice. *Id.* ¶ 248.

The FDA found similar deviations from the cGMPs after inspecting Aurobindo's foreign manufacturing facility. Specifically, it found that "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product"; there were no "written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess"; and "[l]aboratory controls [did not] include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." *Id.* ¶ 256. A 2017 inspection revealed that "[p]rocedures designed to

[3] To be clear, the term "cGMP" is a term of art and refers to current Good Manufacturing Practices

prevent microbiological contamination of drug products purporting to be sterile are [were] established." *Id.* ¶ 258.

The FDA's inspections of Mylan's manufacturing facilities fared no better. Throughout 2014 and 2015, the FDA inspected Mylan's Indian manufacturing facilities and discovered that it had failed to "establish and follow written procedures to prevent microbiological contamination of drug products . . . [provide] assurance that the manufacturing facilities were sterile, and . . . thoroughly investigate unexplained discrepancies in batches or whether the components met specifications." *Id.* ¶ 280. In 2015, a former Mylan employee sat down with the FDA and informed them that "in order to generate passing results for some drug products, Mylan had manipulated the testing, by switching the tests from batch testing to pilot batches." *Id.* ¶ 282.

The whistleblower also claimed that "the Mylan team had evolved its fraudulent methods to evade detection. For example, instead of deleting manipulated data from the plant's software systems, which would have left a trail of metadata that could be uncovered by the FDA, plant managers were deliberately corrupting the data they wanted to hide." *Id.* ¶ 283. A year later, the FDA inspected Mylan's manufacturing facility and found "evidence that the plant's software system was riddled with error messages showing 'instrument malfunction,' or 'power loss.'" *Id.* ¶ 286. Mylan explained that "the high number of data error messages (42 over a seven-day period) . . . may have been [due to] accidental knocking of cables off of tables, or through electronic loss of signals." *Id.* ¶ 287.

The FDA's inspection of Hetero's manufacturing facilities in 2016 revealed "that Hetero Quality Assurance technicians and 'other individuals' were . . . destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection." *Id.* ¶ 300. During this investigation the FDA also found that "equipment at Hetero was found to have not been cleaned and maintained at appropriate intervals to 'prevent contamination that would alter the safety, identity, strength, quality and purity' of Hetero drug products." *Id.* ¶ 304.

After the recalls, the Manufacturing Defendants' VCDs were tested by the FDA and were found to contain NDMA and NDEA at levels well in excess of the FDA's interim limits. *Id.* at ¶ 251, 266, 311.

1.3 Procedural History

Lawsuits quickly followed the recalls of the VCDs. Approximately, seventy-five actions that were pending in twenty different jurisdictions were consolidated and transferred to this Court for pretrial proceedings. Doc. No. 617. These jurisdictions included: (1) Louisiana; (2) New York; (3) New Jersey; (4) Missouri; (5) Tennessee; (6) Illinois; (7) California; (8) Alabama; (9) Arkansas; (10) Florida; (11) Georgia; (12) Indiana; (13) Massachusetts; (14) Minnesota; (15) Ohio; (16) Pennsylvania; (17) Mississippi; (18) Kansas; (19) Kentucky; and (20) Michigan. After this Court issued its direct filing order,

approximately seven hundred and nineteen actions (719) were directly filed into this MDL. These cases include both individual and class actions.

Plaintiffs filed three Master Complaints in this MDL for administrative convenience and asserted a number of claims against the Manufacturer, Wholesaler, and Pharmacy Defendants. In the ELMC, plaintiffs allege six fraud based claims: (1) affirmative misrepresentation, omission, and concealment individually and on behalf of consumer class members against all defendants; (2) affirmative misrepresentation, omission, and concealment individually and on behalf of the TPP class members against all defendants except the pharmacy defendants; (3) negligent misrepresentation and omission individually and on behalf of consumer class members against all defendants; (4) negligent misrepresentation and omission individually and on behalf of TPP class members against all defendants except the pharmacy defendants; (5) violation of the state consumer protection statutes individually and on behalf of consumer class members against all defendants; and (5) violation of the state consumer protection statutes individually and on behalf of the TPP class members against all defendants except the pharmacy defendants. In the MMMC, plaintiffs allege one claim of fraud/fraudulent concealment individually and on behalf of the class against all defendants. In the PIMC, plaintiffs allege fraud, negligent misrepresentation, and violation of the state consumer protection statutes claims against all defendants.

Plaintiffs also brought products liability claims against the defendants. In the PIMC, plaintiffs asserted a strict liability design defect, manufacturing defect, and failure to warn claim. In the MMMC, plaintiffs only asserted strict liability manufacturing defect and failure claims. Plaintiffs did not assert any products liability claims in the ELMC.

The Manufacturer, Wholesaler and Pharmacy defendants all moved to dismiss the Master Complaints under Rule 12(b)(6) for various claim specific deficiencies. The Wholesalers and Pharmacy Defendants also argued that all products liability claims against them should be dismissed under various state innocent seller statutes.

2.0 LEGAL STANDARD

Federal Rule of Civil Procedure ["Fed. R. Civ. P." or "FRCP"] 12(b)(6) allows a court to dismiss an action for failure to state a claim upon which relief can be granted. When evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) [*quoting Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)]. In other words, a complaint survives a motion to dismiss if it contains enough factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

To make this determination, courts conduct a three-part analysis. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the Court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Id.* [*quoting Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)]. Second, the Court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* [*quoting Iqbal*, 556 U.S. at 680]. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* [*quoting Iqbal*, 556 U.S. at 678]. Finally, "when there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* [*quoting Iqbal*, 556 U.S. at 679]. A complaint cannot survive a motion to dismiss where a court can only infer that a claim is merely possible rather than plausible. *Ibid.*

3.0 DISCUSSION: CHOICE OF LAW GENERALLY

Defendants move to dismiss the Master Complaints under Rule 12(b)(6) on a variety of grounds. Before considering any of the arguments raised by the defendants, we must address the threshold issue, which neither party squarely addressed, of the appropriate law to apply to each of plaintiffs' claims. This choice of law question, although often overlooked, may have important implications for the viability of class certification.

For the federal claims and issues the answer is relatively straightforward: this Court must apply the law of the Third Circuit. *In re Korean Air Lines Disaster of September 1, 1983*, 829 F.2d 1171, 1176 (D.C.Cir.1987) ["the law of a transferor forum on a federal question ... merits close consideration, but does not have stare decisis effect in a transferee forum situated in another circuit."], *judgment aff'd. by Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989); *Eckstein v. Balcor Film Investors*, 8 F.3d 1121, 1126 (7th Cir.1993) ["We agree with Korean Air Lines that a transferee court normally should use its own best judgment about the meaning of federal law when evaluating a federal claim. . . ."].

The choice of law issue for the state law claims in the Master Complaints is more circuitous, however. When a district court's jurisdiction is based upon diversity of citizenship, the court must apply the choice-of-law rules of the forum state. *Klaxon v. Stentor Elec. Mfg.*, 313 U.S. 487, 496 (1941). When actions are transferred to a court as part of a multi-district litigation, the forum state is the state where the action was first filed. *In re Grand Theft Auto Video Game Consumer Litig.*, 251 F.R.D. 139, 147 (S.D.N.Y.2008). Thus, a court must make an independent choice of law determination for each state in which an action was originally filed even if it was subsequently transferred to the MDL court. For cases that are directly filed into the MDL court, the MDL court applies the law of the state in which it sits absent a stipulation by the parties.

There were a total of seventy-five actions pending in twenty different jurisdictions that were consolidated and transferred to this Court for pretrial proceedings. Doc. No. 617. Additionally, seven

hundred and nineteen actions (719) were directly filed into this MDL. A total of about 710 pending actions remain in this MDL. The transferred and direct filed cases are comprised of both individual and class actions.

While actions that were directly filed in this Court would normally require application of New Jersey law, the parties "stipulate[d] and agree[d] that the direct filing of an action in this MDL pursuant to this CMO in the District of New Jersey shall have no impact on the choice of law that would apply otherwise to an individual action had it been originally filed in another district court and transferred to this Court pursuant to 28 U.S.C. § 1407." Doc. No. 76 (Case Management Order 3) ¶2.7). This Court also ordered that for any actions directly filed in this MDL, the short form complaint shall "contain a designation of venue, which will be the presumptive place of remand absent an agreement otherwise among the Parties or a determination by the Court that the place of remand should be elsewhere based upon good cause." Doc. No. 76 ¶ 2.4).

The short-form complaints directly filed in this MDL contained designations of venue that spanned the fifty states plus the District of Columbia and Puerto Rico. Therefore, because of this stipulation and order, for the actions directly filed in this MDL, we must conduct a choice of law analysis for each of the fifty states plus the District of Columbia and Puerto Rico. This is so even though our prior opinion limited the class actions claims in the ELMC and MMMC to those twenty-one states where the named plaintiffs resided or were injured, because the individual actions, whether transferred to or directly filed in the MDL, span all fifty states plus the District of Columbia and Puerto Rico.

While this choice of law analysis may seem like a particularly laborious task, the answer is quite simple—the law of each plaintiffs' home state should be applied. It is nearly an unassailable conclusion that the laws of the fifty states with respect to some of the causes of actions will conflict and affect the outcome of the case. Even a cursory review of the law confirms this conclusion. For instance, under New York's law for negligent misrepresentation a plaintiff is required to show either privity of contract between the parties or a relationship approaching privity, while Texas does not require such a showing. *Compare Parrott v. Coopers & Lybrand LLP*, 95 N.Y.2d 479, 483, 718 N.Y.S.2d 709, 741 N.E.2d 506 (N.Y.2000) [*stating* that in a claim of negligent misrepresentation a plaintiff must show "either actual privity of contract between the parties or a relationship so close as to approach that of privity."] with *Averitt v. PriceWaterhouseCoopers L.L.P.*, 89 S.W.3d 330, 335 (Tex.App.2002) [*stating* that privity is not required to hold an accountant liable to a third party arising from the accountant's misrepresentations).

Likewise, some states do not limit negligence per se claims to statutes that contain express private right of actions. *See First Choice Fed. Credit Union v. Wendy's Co.*, No. CV 16-506, 2018 WL 2729264, at *5 (W.D. Pa. 9 May 2018), report and recommendation adopted, No. CV 16-506, 2018 WL 2721998 (W.D. Pa. 6 June 2018) [*agreeing* there is a conflict between Ohio law and the laws of Alabama and Mississippi because these latter states do not limit negligence per se to states that contain express

private right of actions]. Similarly, the differences between many states' laws for common law fraud abound. *Compare Walid v. Yolanda for Irene Couture, Inc.*, 425 N.J. Super. 171, 180, 40 A.3d 85, 90 (App. Div. 2012) [*noting* that "[t]o establish common-law fraud, a plaintiff must prove: '(1) a material misrepresentation of a presently existing or past fact; (2) *knowledge or belief* by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages.' " (*quoting Banco Popular North America v. Gandi*, 184 N.J. 161, 172–73, 876 A.2d 253 (2005))] *with DeArmitt v. New York Life Ins. Co.*, 2013 PA Super 161, 73 A.3d 578, 591 (2013) [*stating* "[t]o prove a claim for common law fraud, a party 'must show: (1) a representation; (2) material to the transaction at issue; (3) made falsely, with either knowledge or *reckless disregard* of its falsity; (4) with the intent [of] misleading another person or inducing justifiable reliance; and (5) an injury caused by the reliance.' " (*quoting Bennett v. A.T. Masterpiece Homes at Broadsprings*, LLC, 40 A.3d 145, 152 n. 5 (Pa. Super. 2012))].

The next step in any choice of law analysis would require us to determine which state's laws should apply, either through a fact intensive inquiry under the most significant relationship test in the Restatement (Second) Choice of Law, the simple *lex loci delicti* [law of the place where the wrong occurred] rule, or under some hybrid form of place- with-the-greatest- interest analysis. But under any choice of law test, the answer remains the same: the law of the plaintiffs' home state should apply. The plaintiffs most likely purchased the VCDs in the state where they reside or even, if they purchased the VCDs elsewhere, they consumed the VCDs and were injured in their home state. Therefore, each plaintiffs' home state has the greater interest in protecting its consumers from in-state injuries by foreign corporations and in delineating the scope of recovery for its citizens than any other state does. Indeed, this is not a novel conclusion as many courts have made similar findings when faced with multi-district litigation involving individual and class actions. *See, e.g., In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 291 F.R.D. 13, 18 (D. Mass. 2013) [*concluding* the law of the plaintiffs' home states should apply for claims of fraud and misrepresentation in multi-district litigation); *In re Vioxx Prod. Liab. Litig.*, 478 F. Supp. 2d 897, 906 (E.D. La. 2007) [*finding* the law of each plaintiff's home state would apply for claims of negligence, fraud, and breach of warranty because that is where the plaintiffs resided when they were prescribed the drug, where they ingested it, and allegedly injured]; *In re Actiq Sales & Mktg. Practices Litig.*, 307 F.R.D. 150, 167 (E.D. Pa. 2015) [*concluding* the unjust enrichment laws of the third-party payor's home states applied because that was where TPPs made payments for the prescriptions and where their beneficiaries purchased the prescriptions]; *Maniscalco v. Brother Int'l (USA) Corp.*, 709 F.3d 202, 209 (3d Cir. 2013) [*finding* the law plaintiff's home state had the most significant relationship because that is where he received and relied on the defendant's alleged misrepresentations] ; *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011) [*concluding* the consumer protection laws of the class members home states will govern their claims because no state has a stronger interest in

regulating deceptive and fraudulent conduct than the state where the consumers are harmed]; *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 457 (D.N.J. 1998) [*explaining* the court would need to apply the law of each of the states from which the plaintiffs hailed because each plaintiff's home state had an interest in protecting consumers from in-state injuries caused by foreign corporations].

Accordingly, for each plaintiff, the Court will apply the law of the plaintiff's home state.

4.0 FRAUD CLAIMS

In all three Master Complaints, plaintiffs allege defendants committed fraud by making affirmative misrepresentations, negligent misrepresentations, material omissions, and/or fraudulently concealing material information and that this conduct also violates state consumer protection statutes. All defendants move to dismiss these claims for failure to satisfy Rule 9(b)'s heightened pleading standard and other claim specific deficiencies. For the sake of clarity, we address each of the defendants' arguments separately.

4.1 Manufacturing Defendants: ELMC, PIMC, and MLMC claims[4]

The Manufacturing Defendants argue the fraud claims should be dismissed because they do not meet the heightened pleading standard of FRCP 9(b) as: (1) there are no facts showing "how any consumer was defrauded by any Defendant because of the alleged nitrosamine impurities in the VCDs"; (2) the alleged misstatements are not pled with specificity; and (3) they routinely lump together all defendants without pleading particular facts for their misconduct. They also contend the Master Complaints fail to satisfy the knowledge or scienter element because they do not allege beyond conclusory allegations that defendants knew their VCDs were contaminated with carcinogens. In response, plaintiffs maintain the Master Complaints adequately allege fraud against the Manufacturing Defendants because they set forth the "who, what, where, when, and why" for each Manufacturing Defendant. Plaintiffs rebut the scienter argument by arguing they do not need a "smoking gun" but simply circumstantial evidence of knowledge, which they have.

While there are certainly differences across the fifty states in terms of common law fraud claims,[5] the basic elements are virtually the same. A plaintiff must prove:

(1) defendant made a materially false representation;

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[4] Since the Manufacturing Defendants' challenge to Plaintiffs' fraud claims appears limited to affirmative misrepresentation, our analysis is similarly limited.

[5] *Kearney v. Bayerische Motoren Werke Aktiengesellschaft*, No. CV1713544WHWCLW, 2018 WL 4144683, at *6 (D.N.J. Aug. 29, 2018).

(2) had knowledge of its falsity, believed it to be false, or made it with reckless indifference as to its falsity;
(3) with the intent to deceive;

(4) plaintiff acted in reliance on the statement; and

(5) plaintiff suffered damages as a result of the reliance.[6]

Despite the similarities among states with regard to the substantive elements that must be proven for a plaintiff to succeed on a common law fraud claim, there are still subtle nuances that are beyond the purview of this opinion. This is because the Manufacturing Defendants' arguments do not contest the legal sufficiency of plaintiffs' complaints under state law but rather under federal law—whether plaintiffs' allegations satisfy Rule 9(b)'s particularity requirement. *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec.*, LLC, 797 F.3d 160, 182 n.14 (2d Cir. 2015) [*noting* that "[w]hile the substantive elements of common-law fraud that must be *proven* are a matter of state law, what must be *pleaded* and with what level of particularity are governed by Rules 9(b) and 12(b)(6)."] Therefore, to determine whether Plaintiffs have satisfied Rule 9(b)'s particularity requirement, we consult 3rd Circuit precedent.

FRCP 9(b) provides "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. Rules Civ. Proc. 9(b). For fraud claims, Rule 9(b) imposes a heightened pleading requirement, over and above that of Rule 8(a). *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 318 (D.N.J. 2014). This heightened standard requires the plaintiff to "state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir.2007). Generally, to satisfy this standard, the plaintiff must plead the date, time, and place of the alleged fraud along with who made the misrepresentation to whom and the general content of the misrepresentation. *Id.*; *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir.2006) ["Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue."]. A plaintiff must also "identify the speaker of the allegedly fraudulent statements." *Riachi v. Prometheus Grp.*, 822 F. App'x 138, 142 (3d Cir. 2020). However, even if the plaintiff does not plead the "date, place, or time" of the fraud, they may satisfy this heightened standard by injecting precision and some measure of substantiation into their allegations. *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 319 (D.N.J. 2014).

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[6] *Washington Courte Condo. Ass'n-Four v. Washington-Golf Corp.*, 267 Ill. App. 3d 790, 815, 643 N.E.2d 199, 216 (1994); *Swersky v. Dreyer & Traub*, 219 A.D.2d 321, 326, 643 N.Y.S.2d 33, 36 (1996); *In re Wayport, Inc. Litig.*, 76 A.3d 296, 323 (Del. Ch. 2013); *Saucier v. Countrywide Home Loans*, 64 A.3d 428, 438 (D.C. 2013); *Nelson v. Najm*, 127 S.W.3d 170, 174 (Tex. App. 2003); *M&D, Inc. v. W.B. McConkey*, 231 Mich. App. 22, 27, 585 N.W.2d 33, 36 (1998); *Waldridge v. Homeservices of Kentucky, Inc.*, 384 S.W.3d 165, 171 (Ky. Ct. App. 2011). These citations are not exhaustive, but rather, illustrative of the virtual uniformity of the, basic elements of common law fraud.

Rait v. Sears, Roebuck & Co., No. CIV. A. 08-2461 (JLL, 2009 WL 250309, (D.N.J. 3 Feb. 2009) is an example where the plaintiffs did not meet the pleading requirement of particularity under Rule 9. Consumers filed a class action against Sears alleging it violated the New Jersey Consumer Fraud Act and committed common law fraud by selling a defective garage door opener. *Id.* at *1. Plaintiff Rait alleged she decided to purchase the Sears Craftsman brand of garage door opener after comparing various models on Sears' website because it .had "double lights and [she] wanted her garage to be well lit." *Ibid.* Within three weeks of the product being installed, the light went out. *Ibid.* She replaced the bulb, but it kept burning out. *Ibid.* In total, she replaced the bulb six times. *Id.* She alleged there were "numerous complaints on various internet sites as well as Sears' own website regarding similar issues with Sears Craftsman brand garage door openers." *Ibid.*

Nonetheless, the Court granted Sears' motion to dismiss for failure to satisfy Rule 9(b)'s particularity requirement, finding plaintiff had alleged only broad conclusions[7] and dismissed the common law fraud and N. J. Consumer Fraud Act claims. The Court reasoned the broad conclusions in the complaint did not put Sears on specific notice of the basis for plaintiff's allegations. *Id.* at *4.

In contrast to the consumer class plaintiffs' claims in *Rait*, plaintiffs here have sufficiently injected precision and a large measure of substantiation into their allegations. They posit at least two theories of fraud with respect to the Manufacturing Defendants. First, Plaintiffs allege the Manufacturing Defendants misrepresented that the VCDs were therapeutically equivalent to the reference listed drug, complied with cGMPs, were unadulterated, and properly branded. The second theory is simply the inverse of the first: the Manufacturing Defendants failed to disclose that the VCDs were not therapeutically equivalent to the reference listed drug, did not comply with cGMPs, were adulterated and improperly branded. Plaintiffs then buttress these two theories with specific factual averments.

In the ELMC, MMMC, and PIMC, Plaintiffs allege the Manufacturing Defendants misrepresented to consumers and TPPs that the VCDs were therapeutically equivalent to the reference listed drug by seeking and receiving inclusion in the Orange Book and by affixing an FDA approved label to their products that is the same as the RLD. Doc. No. 398, ELMC ¶¶ 361–64; Doc. No. 123,MMMC ¶¶ 318–21; and Doc. No. 122, PIMC ¶¶ 346–49. Specifically, by securing FDA approval to market their generic VCDs in the United States as an Orange Book listed drug, the Manufacturing Defendants represented their VCDs were therapeutically equivalent to the reference listed drug. Similarly, by presenting consumers with an FDA approved label, the Manufacturing Defendants represented their VCDs were consistent with the safety, quality, purity, identity, and strength characteristics reflected in that label. Plaintiffs further

[7] These included: Sears "violated the CFA [N.J. Consumer Fraud Act] by failing to properly disclose to Plaintiff . . . the terms, conditions, and fees associated with services and repairs to their Sears Craftsman brand garage door openers" or "Plaintiff is aware of numerous complaints on various internet sites as well as Sears' own website regarding similar issues with Sears Craftsman bran garage door openers." *Rait,* 2009 WL 250309 at *4.

allege these representations were false because the presence of NDMA and NDEA rendered the VCDs non-bioequivalent to the RLD and therefore not therapeutically equivalent to the RLD. Doc. No. 398, ELMC ¶ 366; Doc. No. 123, MMMC ¶ 323; Doc. No. 122, PIMC ¶ 351. Likewise, the representation that the VCDs were consistent with the characteristics reflected in the FDA approved label was false because NDMA and NDEA were not listed as an ingredient on the labels.

Plaintiffs also allege the Manufacturing Defendants misrepresented through their websites, brochures, and other marketing materials to consumers and the TPPs that the VCDs were cGMP compliant and did not contain any ingredients beyond those identified on the FDA approved label. Doc. No. 398, ELMC ¶ 365; Doc. No. 123, MMMC ¶ 322; Doc. No., 122, PIMC ¶ 350. Plaintiffs then explicitly cite to and quote the misrepresentations in the Manufacturing Defendants' websites, brochures, and other promotional materials.

For instance, on ZHP's website it represented that it had "established an independent, strict and sound quality management system in accordance with GMP." Doc. No. 398, ELMC ¶ 376; Doc. No. 123, MMMC ¶ 333; Doc. No. 122, PIMC ¶ 356. Prinston and Solco, subsidiaries of to ZHP, also list valsartan as the equivalent to Diovan (the patented Orange Book drug). Doc. No. 398, ELMC ¶¶ 378, 381; Doc. No. 123, MMMC ¶¶ 335; 338; Doc. No. 122, PIMC ¶¶ 358, 361.

On its website, Hetero describes itself as having "around 18 state-of-the-art manufacturing facilities, which are cGMP compliant and have been approved by various . . . regulatory authorities like US FDA." Doc. No. 398, ELMC ¶ 383; Doc. No. 123, MMMC ¶ 340; Doc. No. 122, PIMC ¶ 363. Hetero also represents that its generic drugs are "copies of brand-name drugs and are the same as those brand name drugs in dosage, form, safety, strength, route of administration, quality, performance characteristics and intended use." Doc. No. 398, ELMC ¶ 385; Doc. No. 123, MMMC ¶ 324; Doc. No. 122, PIMC ¶ 365.

Camber, a subsidiary of Hetero, also compares its valsartan to Diovan on its website. Doc. No. 398, ELMC ¶ 386; Doc. No. 123, MMMC ¶ 343; Doc. No. 122, PIMC ¶ 366. Plaintiffs then allege the representations by the Manufacturing Defendants that VCDs did not contain any ingredient beyond those listed on the label was false because the VCDs contained NDMA and NDEA which was not listed on the FDA approved label or contained in a RLD. Doc. No. 398, ELMC ¶ 366; Doc. No. 123, MMMC at ¶ 323; Doc. No. 122, PIMC at ¶ 351. Likewise, they allege the representation that the VCDs were cGMP compliant was also false because the Manufacturing Defendants' repeatedly deviated from those standards. Doc. No. 398, ELMC ¶ 233–311; Doc. No. 123, MMMC ¶ 186–265; Doc. No. 122, PIMC ¶ 266–345. These averments are specific enough to satisfy Rule 9(b)'s particularity requirement and put the Manufacturing Defendants on notice of the precise misconduct with which it is charged.

With respect to the Manufacturing Defendants' argument that plaintiffs have failed to satisfy the knowledge or scienter requirement, we disagree. Rule 9(b) states "[m]alice, intent, knowledge and other conditions of a person's mind may be alleged generally." Courts must be sensitive to the fact that

application of Rule 9(b) prior to discovery 'may permit sophisticated defrauders to successfully conceal the details of their fraud.'" *Craftmatic Securities Litigation v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989). Thus, courts have relaxed this rule when the factual information is peculiarly within the defendant's knowledge or control. *Ibid.* Even under this less restrictive application of the rule, however, plaintiffs must still allege facts that give rise to an inference of knowledge or recklessness. *Kearney v. Bayerische Motoren Werke Aktiengesellschaft*, No. CV1713544 WHW/CLW, 2018 WL 4144683, at *11 (D.N.J. 29 Aug. 2018). In other words, circumstantial evidence is sufficient to meet Rule 9(b)'s standard. *Caspersen as Tr. for Samuel M.W. Caspersen Dynasty Tr. v. Oring*, 441 F. Supp. 3d 23, 40 (D.N.J. 2020). *See, e.g.*, *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256 (3d Cir. 2006).[8]

Plaintiffs' allegations against the Manufacturing Defendants are sufficient to raise an inference of knowledge or, at the very least, recklessness. Just as plaintiffs in *In re Suprema Specialties, Inc. Sec. Litig* set forth allegations showing how the auditor failed to comply with GAAP and ignored classic red flags to at least marginally competent business managers and accountants, so have Plaintiffs here set forth a litany of allegations showing how of each of the Manufacturing Defendants violated cGMPs and then disregarded significant indications of contamination after violating good manufacturing practices. In other words, plaintiffs have alleged a sequence of cause and effect that defendants, had they been even marginally diligent and/or forthright, should have and would have noticed and responded to.

For instance, plaintiffs allege in May of 2017, the FDA inspected ZHP's foreign manufacturing facility and found that it "repeatedly re-tested out of specification . . . samples until obtaining a desirable result" and that "impurities occurring during analytical testing are not consistently documented/quantitated." The FDA also found that ZHP also failed "to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API." ZHP had "approved a [V]alsartan API process change . . . that included the use of the solvent" but "failed to adequately assess

[5] Here the Third Circuit found that allegations of an auditor's violation of Generally Accepted Accounting Principles ["GAAP"} coupled with allegations that red flags were ignored were sufficient to raise an inference of knowledge or recklessness. *In re Suprema Specialties, 438 F.3d* at 281. Two institutional investors and individual investors brought an action against an auditor of an all-natural gourmet cheese company for violations of Section 10(b) of the Securities and Exchange Act of 1934. *Id.* at 263. In 2000 and 2001, the company reported dramatic growth in sales and receivables, and the auditor issued an unqualified opinion substantiating these reports. *Id.* at 264, 267. Ultimately, it was revealed the company had fabricated millions of dollars in cheese sales and engaged in other fraudulent schemes. *Id.* at 265. To show the auditor had knowledge of or willfully turned a blind eye to the company's fraud, the plaintiffs alleged the auditor failed to comply with specific GAAP and ignored numerous red flags. *Id.* at 280. The plaintiffs then explained in detail which red flags the auditor had ignored, which included the auditor 's ignoring the company's report of astronomical growth in net sales, gross margin, and net earnings despite the company's negative ash flow. *Ibid.* Likewise, the company's required annual report to the Securities and Exchange Commission, its 10–K, made no mention that it was engaged in the purchase and resale of bulk cheese from domestic suppliers. However, a cursory review of the company's check register, vendor invoices, and purchasing records revealed that two-thirds of company revenue for that year was derived from such sales. *Ibid.* Similarly, the company had weak internal controls, which should have led the auditor to investigate further before issuing unqualified audit opinions. *Ibid.* Based on these accounting violations and the general disregard for obvious indications of fraud, the Court concluded that the auditor either knew or willfully turned a blind eye to the fraud at company. *Id.* at 283.

the potential formation of mutagenic impurities [, such as NDMA,] when [it] implemented the new process." The FDA's inspection of Aurobindo's foreign manufacturing facilities revealed similar deviations from the cGMPs; it found that "[a]n [redacted] Field Alert was not submitted within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product." Likewise, the FDA found that Aurobindo's laboratory controls did not include the "establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity." Nor were there "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile." This lack of significant internal controls is no different from those in *In re Suprema Specialties, Inc. Sec. Litig.* (*See supra* fn. 8) and therefore lends similar credence to Plaintiffs' claims of knowledge.

Moreover, plaintiffs' allegations show there were significant attempts to manipulate, disregard, or destroy data. For instance, a Mylan whistleblower identified specific applications for drugs that were due to be launched into the U.S. market and claimed that in order to generate passing results for some drug products, Mylan had manipulated the testing, by switching the tests from batch testing to pilot batches. Similarly, "during an inspection of an oral solid dose drug product manufacturing facility, the FDA observed, through closed circuit TV surveillance, that Hetero Quality Assurance technicians and 'other individuals' were recorded destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection." The list of allegations goes on. We need not recite them all to conclude that plaintiffs allegations surpass an inference of ordinary negligence and reasonably suggest that the Manufacturing Defendants either knew of or recklessly disregarded the contamination.

Indeed, what makes Plaintiffs allegations so convincing is that they are required to allege ONLY knowledge generally. Indeed, plaintiffs' allegations here would meet the standard imposed in *In re Suprema Specialties, Inc. Sec. Litig*, a higher standard than that imposed under general common law fraud because the claim arose under the PLSRA. *See In re Suprema Specialties, Inc. Sec. Litig*., 438 F.3d 256, 277 (3d Cir. 2006); *Bonomo v. Nova Fin. Holdings, Inc*., No. CIV.A. 11-4762, 2012 WL 2196305, at *5 n.4 (E.D. Pa. June 15, 2012). Ultimately, since plaintiffs' allegations rise to the level of the higher standard asserted in *In re Suprema Specialties, Inc. Sec. Litig*., there can be no doubt that plaintiffs have properly pleaded their fraud-based claims against the Manufacturing Defendants in all three Master Complaints.

Finally, defendants argue that plaintiffs' concede defendants have no knowledge of the contamination when they allege that had defendants adhered to FDA guidelines, they "would have found the NDMA and NDEA contamination almost immediately." Defendants emphasis on the words "would have found," ignores the phrase "almost immediately." Plaintiffs are asserting that defendants never discovered the contamination, only that they would have discovered it sooner had they followed FDA

guidelines. This allegation does not concede a lack of knowledge, rather it leaves open the possibility that defendants discovered the contamination sometime before the voluntary recalls. Thus, defendants' attempt to squeeze a concession out of the phrase "would have found" falls flat.

Accordingly, the Court **DENIES** the Manufacturing Defendants' motion to dismiss the **fraud-based claims in all three Master Complaints**.

4.2 Wholesaler Defendants and Pharmacy Defendants: Fraud-Based Claims[9] in all three Master Complaints

The Wholesaler Defendants argue Plaintiffs' fraud-based claims should be dismissed for several reasons.[10]

First, the fraudulent misrepresentation claims should be dismissed because plaintiffs do not allege the "who, what, where, or when" necessary to satisfy the particularity requirement of Rule 9(b), and .

> specifically, plaintiffs plead no facts that show Wholesalers' scienter or imputer scienter, that is, Wholesalers "knew or reasonably should have known" their representations were false or misleading, and also plead no facts that show Plaintiffs' reliance on such non-existent scienter.

Second, the negligent misrepresentation claims should be dismissed because plaintiffs' boilerplate allegations that the "defendants were negligent" in so misrepresenting fail to identify specific misrepresentations.

The Pharmacy Defendants argue plaintiffs' fraud-based claims should be dismissed for this reason: that plaintiffs have failed to plead facts sufficient to demonstrate Pharmacies' actual or constructive knowledge of the contamination.

In response, plaintiffs contend there is no need to plead the Wholesalers or Pharmacy Defendants' state of mind with specificity because plaintiffs have used alternative means of injecting precision and substantiation into their fraud allegations, which include:

- each Wholesaler and Pharmacy Defendant failed to test / confirm the purity or bioequivalence of the VCDs, they distributed through the drug supply chain;

- that Wholesaler and Pharmacy Defendants knew / should have known of the contamination, based on information provided by the Manufacturing Defendants; and

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[9] By "fraud-based claims" we mean fraudulent concealment, fraud by omission, affirmative misrepresentations, and consumer fraud statutes. Rule 9(b)'s particularity requirement applies to each of these claims with the exception of the fraud by omission claim. *DeFrank v. Samsung Elecs. Am., Inc.*, No. CV1921401KMJBC, 2020 WL 6269277, at *6 (D.N.J. Oct. 26, 2020); *Byrnes v. DeBolt Transfer, Inc.*, 741 F.2d 620, 626 (3d Cir.1984). Even though Rule 9(b) is relaxed in the context of fraud by omission, Plaintiffs' have failed to satisfy Rule 8 with respect to the knowledge requirement for their omission claims.

[10] Since we agree with the Wholesaler Defendants that plaintiffs' fraud-based claims fail to meet the Rule 9(b) pleading requirement of particularity as well as the requirements of Rule 8, Wholersalers' other arguments need not be addressed..

- Wholesaler and Pharmacy Defendants expressly or impliedly warranted the VCDs they sold were not contaminated.

Specifically, the ELMC alleges only the following with respect to the Wholesaler Defendants and the Pharmacy Defendants:

> Each Wholesaler Defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs. Wholesaler Defendants knew or should have known, based on information provided or available from each Manufacturing Defendant, of the actual or potential adulteration, misbranding, or contamination of VCDs they purchased from Manufacturing Defendants. Wholesaler Defendants expressly or impliedly warranted the VCDs they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case.

Doc. No. 398, ELMC ¶¶ 410, 411).

The allegations in the PIMC are even more conclusory. "Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs" (Doc. No. 122, PIMC ¶ 388), which is then followed by boilerplate legal conclusions. *Id*. ¶ 497–509.

Moreover, the MMMC cannot be read to even allege fraud. Contrary to plaintiffs' contention, the MMMC ¶¶ 118 - 120 cannot be read to state the same thing as the block quote from the ELMC stated above. The allegations cited to in the MMMC are merely a list of ways a drug can be adulterated or misbranded.

The Court finds that the fraud allegations in all three Complaints against Wholesaler and Pharmacies fail to satisfy Rule 9(b)'s particularity requirement for several reasons:

- First, the allegations lump all of the defendants together. Collectivized allegations against "defendants" do not put each of the defendants on notice of the roles they each played in the alleged scheme. *Indianapolis Life Ins. Co. v. Hentz*, No. 1:06-CV-2152, 2008 WL 4453223, at *11 (M.D. Pa. Sept. 30, 2008); *Naporano Iron & Metal Co. v. Am. Crane Corp*., 79 F. Supp. 2d 494, 511 (D.N.J. 1999). This failure is detrimental to plaintiffs' fraud claim because notice is the main purpose of Rule 9(b)'s particularity requirement.

-Second, these allegations identify neither the time, place, content of the statement with any level of particularity nor do they inject precision or a measure of substantiation into their allegations other than merely saying so. To wit, the allegations regarding Wholesalers' and Pharmacies' purported misstatements were that these defendants "expressly or impliedly warranted the VCDs they sold were not adulterated, misbranded, or contaminated." (ELMC at ¶ 411).

However, such general allegations that do not identify the specific content of the misstatement with any particularity are insufficient. *In re Diet Drugs (phentermine/fenfluramine/dexfenfluramine) Prod. Liab. Litig.*, No. CIV.A. 00-21044, 2012 WL 1172164, at *3 (E.D. Pa. 9 Apr, 2012) [*finding* Rule 9(b)'s particularity requirement unmet because the general statement that "Wyeth's 'advertising program . . . sought to create the image and impression that the use of [diet drugs] . . . was safe for human use; had no, or no unacceptable, side effects; [and] had fewer side effects than other methods of weight loss" did not specify any alleged misrepresentation).

Third, even though Rule 9 allows knowledge to be alleged generally, this does not give plaintiffs a "license to evade the less rigid—though still operative—strictures of Rule 8." *Ashcroft v. Iqbal*, 556 U.S. 662, 686–87 (2009). Plaintiffs conclusory allegation that the Wholesaler and Pharmacy Defendants' "knew or should have known, based on information provided or available from each manufacturer or Wholesaler defendant, of the actual or potential adulteration, misbranding, or contamination of VCDs they purchased from Manufacturing Defendants" is insufficient to satisfy the strictures of Rule 8. While we are mindful of the informational asymmetry between plaintiffs and defendants, plaintiffs have not even alleged that this information is within the control of defendants.

In addition, plaintiffs' fraud claims in the MMMC against the Wholesaler Defendants also fail for a different reason than not meeting the particularity requirement of Rule 9. In the MMMC (Doc. No. 123, MMMC ¶¶ 368–76), plaintiffs do identify the content of some Wholesalers Defendants' alleged misstatements. However, Wholesalers point out there are no allegations of reliance by the plaintiffs beyond conclusory ones. For instance, plaintiffs cite to statements made in Cardinal Health's Standards of Business Conduct, McKesson's Code of Conduct, and AmerisourceBergen's Code of Ethics and Business Conduct as "warranties" or representations made by Wholesaler Defendants.

Further on in the MMMC ¶483, plaintiffs then allege generally that "Plaintiffs relied on Defendants' representations that the Valsartan they were purchasing and ingesting was safe and free from contamination." However, plaintiffs do not allege when these statements were made, or at what point—if ever—each plaintiff was exposed to these statements. *Dewey v. Volkswagen AG*, 558 F. Supp. 2d 505, 528 (D.N.J. 2008) [*granting* defendants' motion to dismiss the common law fraud claims because the plaintiffs did not allege any facts that showed they relied on the defendants' misstatements on their websites beyond conclusory ones]. Moreover, as these "reliance" facts are indisputably within plaintiffs' control, no further discovery would not enable plaintiffs to allege reliance with any more specificity. Therefore, as plaintiffs have not pleaded reliance with particularity, their fraud claims in the MMMC against the Wholesaler Defendants will be dismissed without prejudice for this reason as well.

Accordingly, the Court **GRANTS** the Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the **fraud-based claims[11] in all three Master Complaints and dismisses these claims WITHOUT PREJUDICE**. Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the fraud-based claims against the Pharmacy Defendants and the Wholesaler Defendants, according to the deadline set forth in the accompanying Order.

4.3 Wholesaler Defendants: Negligent Misrepresentation Claims in all 3 Master Complaints

We agree with Wholesaler Defendants that in the PIMC, plaintiffs' negligent misrepresentation claim is essentially a boilerplate list of legal conclusions. Indeed, in their brief, plaintiffs do not even cite to allegations in the PIMC that support their negligent misrepresentation claim. The negligent misrepresentation claim in the ELMC is also equally devoid of any factual support necessary to satisfy Rule 8. While plaintiffs allege in the ELMC that "Wholesaler Defendants expressly or impliedly warranted [the] VCDs they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case" they do not explain how the Wholesaler or Pharmacy Defendants made these representations.[12] *Innova Hosp. San Antonio, L.P. v. Blue Cross & Blue Shield of Georgia, Inc.*, 995 F. Supp. 2d 587, 606 (N.D. Tex. 2014) (finding the plaintiffs failed to plead sufficient facts to state a claim for negligent misrepresentation because they did not allege how the defendants provided the information to them). Were these representations an implied representation that arises simply by virtue of selling the product without disclosing the contamination? Did the Wholesalers and Pharmacy Defendants make explicit statements regarding the quality of the VCDs? It is altogether not clear. Instead, most of the Master Complaints are devoted to setting forth the Manufacturing Defendants' purported misrepresentations on their websites and in their marketing materials and describing their violations of the cGMPs. What remains is simply a few conclusory allegations against the Pharmacy and Wholesaler Defendants that do not put them on notice of their purportedly illegal conduct.

Accordingly, the Court **GRANTS** the **Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the negligent misrepresentation claims all three Master Complaints and dismisses these claims WITHOUT PREJUDICE**. Plaintiffs may file a motion for LEAVE TO AMEND all three Master Complaints as to the negligent misrepresentation claims against the Pharmacy Defendants and the Wholesaler Defendants, according to the deadline set forth in the accompanying Order.

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[11] *See supra* note 11.

[12] Plaintiffs cite to paragraphs 493 and 494 in the ELMC to support their fraud claims. However, these allegations appear under the claim of fraud and do not appear under the negligent misrepresentation claim. Therefore, we cannot attribute them to plaintiffs' negligent misrepresentation claim. Nor do they appear in the body of the complaint where they could be fairly attributable to any claim.

5.0 STRICT LIABILITY CLAIMS

5.1 DESIGN DEFECT CLAIMS in the PIMC against Manufacturing Defendants

Manufacturing Defendants argue that the design defect claims in the PIMC should be dismissed because:

- plaintiffs do not allege that defendants' designed their VCDs to contain nitrosamines;
- there are no factual allegations to support the other elements of a defective design claim; and
- plaintiffs do not identify any particular aspect of the design as defective nor specify any deviation from the FDA approved design; and

many states do not recognize strict liability design defect claims.

5.1.1 Manufacturing Defect Liability Claims in the PIMC against Manufacturing Defendants

In their opposition, plaintiffs contend the PIMC pleads two alternate design defect theories of liability against the Manufacturing Defendants: a manufacturing defect claim and a design defect claim. The manufacturing defect claim alleges the Manufacturing Defendants introduced dangerous nitrosamines into their VCDs due to inadequate manufacturing practices. The defective design claims allege the Manufacturing Defendants created new VCD designs that included nitrosamines in order to better compete in the market.

We agree with the Manufacturing Defendants that several states do not recognize strict liability design defect claims. *Branham v. Ford Motor Co.*, 390 S.C. 203, 220 n.11 (2010) [noting Delaware, Massachusetts, North Carolina, and Virginia do not recognize strict liability claims at all]; *White v. APP Pharm.*, LLC, No. CIV.A.N10C-04-061CLS, 2011 WL 2176151, at *2 (Del. Super. Ct. 7 Apr. 2011); *Com. v. Johnson Insulation*, 425 Mass. 650, 653, 682 N.E.2d 1323, 1326 (1997); *Bryant v. Adams*, 116 N.C. App. 448, 473, 448 S.E.2d 832, 845 (1994); *Evans v. Nacco Materials Handling Grp., Inc.*, 295 Va. 235, 246, 810 S.E.2d 462, 469 (2018); *Porogi v. Ethicon, Inc.*, No. 3:20-CV-00513 JD-MGG, 2020 WL 4676571, at *6 (N.D. Ind. 12 Aug. 2020) [*explaining* Indiana does not recognize strict liability design defect claims, instead design defect claims under the IPLA sound in negligence); *Keen v. C.R. Bard, Inc.*, No. CV 13-5361, 2020 WL 4873634, at *6 (E.D. Pa. 15 Aug. 2020) [*noting* the Pennsylvania Supreme Court has interpreted the Restatement (Second) of Torts (1965, October 2020 Update) § 402A[13], comment k[14] to bar strict liability claims in the context of prescription drugs].

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[13] This section is titled Special Liability of Seller of Product for Physical Harm to User or Consumer.

[14] Comment k states;

Unavoidably unsafe products.

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified,

Accordingly, the Court **GRANTS** the **Manufacturing Defendants' motion to dismiss the strict liability-manufacturing defect claim in the PIMC that arise under the laws of Delaware, Massachusetts, North Carolina, Virginia, Indiana, and Pennsylvania** and **dismisses these claims WITH PREJUDICE**.[15]

5.1.2 General Design Defect Claims in the PIMC against Manufacturing Defendants

Turning now to the Manufacturing Defendants' arguments that plaintiffs' allegations are legally insufficient to state a viable claim design defect, we disagree. Generally, a manufacturing defect is a mistake in the assembly process, which results in a product that differs from the manufacturer's intended result. *See generally* Restatement (Third) of Torts: Prod. Liab. § 2 (1998, October 2020 Update). A design defect, in contrast, exists when the product is otherwise properly manufactured, but is nonetheless unreasonably dangerous because its attributes can cause unexpected injury. *Ibid.*

Like plaintiffs' fraud-based claims, the basic elements of a defective design claim are nearly uniform. A plaintiff must show:

(1) the product was defectively designed so as to render it unreasonably dangerous;[16]

(2) the defect existed when the product was distributed by and under the control of the defendant; and (3) the defect caused injury to a reasonably foreseeable user. *Guilbeault v. R.J. Reynolds Tobacco Co.*, 84 F. Supp. 2d 263, 268 (D.R.I. 2000); *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 621 (S.D.N.Y. 2012); *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008); *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009); *Branham v. Ford Motor Co.*, 390 S.C. 203, 218, 701 S.E.2d 5, 13 (2010).

Laws of various states differ not as to the pleaded elements but as to the test used to analyze whether a product design was defective. Most state laws rely on the consumer expectation test,[17] others

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notwithstanding the unavoidable high degree of risk which they involve. **Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous**. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. [emphasis added]

[15] The Manufacturing Defendants point to their chart to show which states do not recognize strict liability design defect claims. However, the chart merely shows the states that have adopted the Second or Third Restatement, not those that reject strict liability design defect claims.

[16] Some courts consider the "reasonable alternative design" as a factor in whether the product as designed is unreasonably dangerous while others include it as a separate element.

[17] *See* Tenn. Code Ann. § 29-28-102(8); *Gudmundson v. Del Ozone*, 2010 UT 33, ¶ 47, 232 P.3d 1059, 1071.

the risk-utility analysis,[18] and a few apply both or a hybrid of the two.[19] *Branham v. Ford Motor Co.*, 390 S.C. 203, 221, 701 S.E.2d 5, 14 (2010). States also differ in whether they require the plaintiff to show a reasonable or feasible alternative design. Some do,[20] others do not. [21] We need not provide chapter and verse on the nuances of all fifty states in order to find that plaintiffs have carried their burden of alleging facts that demonstrate the product as designed was not reasonably safe.

For instance, if plaintiffs re-plead their allegations under the NJPLA, they will likely make out a viable design defect claim. *Gremo v. Bayer Corp.*, 469 F. Supp. 3d 240, 255 (D.N.J. 2020). In *Gremo*, an individual brought a design defect claim against numerous companies alleging that their gadolinium-based contrast agents ("GBCAs")—agents administered intravenously by medical professional to enhance the quality of magnetic resonance imaging—caused her "gadolinium toxicity" which resulted in rashes, darkening of the teeth, brain fog or memory loss, and loss of smell. *Id.* at 247. The plaintiff alleged that because naturally occurring gadolinium is toxic, they are bound in either a linear or macrocyclic compound to protect the human body from direct exposure to toxic heavy metal. *Id.* at 250. However, the plaintiff pointed out that linear GBCAs, the type she was exposed to, are less stable and more prone to separation of the gadolinium from its compound (i.e., "de-chelation"). *Id.* She further alleged that macrocyclic GBCAs, which are approved by the FDA and available as an alternative to linear GBCAs, are more stable and less prone to de-chelation. *Id.* The Court found that the plaintiff had properly pled a viable design defect claim under the PLA because she alleged that risks of the defendants' linear GBCAs outweighed their utility, and defendants could have designed each product as a macrocyclic GBCA, which would have minimized or eliminated the risk of harm posed by the products. *Id.* at 256.

Here, Plaintiffs allege "the reason Defendants' manufacturing process produced [NDMA and NDEA] is linked to the tetrazole group that most ARB drugs have. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions." Doc. No. 122, PIMC ¶ 167. They further allege that "the presence of NDMA and NDEA in the valsartan containing drugs is due to a manufacturing change that took place on or around 2012." Doc. No. 122, PIMC ¶ 169. Plaintiffs also

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[18] *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009); *Benefield v. Pfizer Inc.*, 103 F. Supp. 3d 449, 462 (S.D.N.Y. 2015) (applying Georgia law).

[19] *Altman v. HO Sports Co.*, 821 F. Supp. 2d 1178, 1193 (E.D. Cal. 2011); *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 166 (D. Conn. 2012).

[20] *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 745 (W.D. Ky. 2013) (noting Kentucky requires proof of a safer, feasible design alternative for a design defect claim but not at the motion to dismiss stage); *Astoria Energy II LLC v. HH Valves Ltd.*, No. 17CV5724ENVRER, 2019 WL 4120759, at *5 (E.D.N.Y.2 Aug. 2019), report and recommendation adopted, No. 17CV5724 ENVRER, 2019 WL 4091417 (E.D.N.Y.29 Aug. 2019); *Reed v. Pfizer, Inc.*, 839 F.Supp.2d 571, 578 (E.D.N.Y.2012) (granting drug manufacturer's motion to dismiss plaintiffs' design defect claim under New York and West Virginia law because "Plaintiffs do not plead facts alleging the existence of a feasible alternative design that would make the product safer").

[21] *Benefield v. Pfizer Inc.*, 103 F. Supp. 3d 449, 462 (S.D.N.Y. 2015) (applying Georgia law); *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, ¶ 11, 319 Wis. 2d 91, 103, 768 N.W.2d 674, 680.

allege that "NDMA and NDEA both have the ability to cause cancer" and as a result of "Plaintiffs' ingestion of the VCDs, plaintiffs developed and were diagnosed with cancer." Doc. No. 122, PIMC ¶¶ 215, 394). Plaintiffs then state that "[t]he risks of these drugs outweighed their benefits when used for the purposes and in the manner intended . . . by these Defendants" and point to a reasonable alternative design that would avoid the risk associated with the current VCDs—the original FDA approved VCDs that are true bioequivalents to Diovan. Doc. No. 122, PIMC ¶ 454). These allegations are more than sufficient to demonstrate that the VCDs as designed are not reasonably safe. Plaintiffs have identified the manufacturing change—the introduction of a different solvent—as the defect in the design and alleged that it produced probable human carcinogens, NDMA and NDEA, which caused cancer. And like the plaintiff in *Gremo*, plaintiffs have suggested that the Manufacturing Defendants could design their VCDs in accordance with the FDA approved design which would reduce or eliminate the risk of harm posed by the current VCDs.

The Manufacturing Defendants' arguments are overly formalistic and again attempt to unduly narrow the field of focus by pointing out a single flaw in the complaint. They argue that the PIMC does not identify any aspect of the design as defective and does not specify any deviation from the FDA approved design.

The decision in *Flores v. Youm*, 69 Misc. 3d 1216(A), 133 N.Y.S.3d 786 at *2 (N.Y. Sup. Ct. 2020) provides a particularly apt explanation of defendants' arguments. In *Flores*, the Court dismissed the plaintiff's design defect claim because she merely alleged the results of a design defect, instead of the defect that caused the result.. The plaintiff brought a design defect claim against a company alleging that she was injured from the use of prosthetic components that were used during her left knee replacement surgery. *Id.* at *1. The plaintiff alleged that the "left knee prosthesis prematurely loosened, failed and caused plaintiff injuries and damages." *Id.* at *2. The Court noted that while the allegation that the "left knee prosthesis prematurely loosened" may demonstrate the results of a design defect, it does not describe the design defect that caused the premature loosening. *Ibid.* Therefore, since the plaintiff's allegations did not put the defendants on notice of the product's defect, the claim was dismissed. *Ibid.*

Plaintiffs do indeed fail to identify the defect under the subsection of the PIMC entitled "Strict Liability-Design Defect." They allege "Defendants' drugs were defectively designed because the design was unsafe for the purposes intended by Defendants" and "[t]hese drugs were designed in a way that caused consumers to suffer injuries including, but not limited to cancer."(Doc. No. 122, PIMC ¶¶ 453, 455. Like the *Flores* plaintiff, plaintiffs here allege the results of a design defect, but not the actual defect itself. Nonetheless, this is not fatal to plaintiffs' claim because, as just noted above, they have supported these legal conclusions with factual allegations. Therefore, this flaw which defendants have homed in on does not prevent plaintiffs from stating a viable design defect claim.

Lastly, defendants' argument that plaintiffs have not specified any deviation from the FDA approved design is factually incorrect. Plaintiffs do allege that the design of the VCDs deviated from the FDA approved design by alleging that "when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new (and unapproved) drug." Doc. No. 122, PIMC 218. Plaintiffs further allege the VCDs manufactured by defendants contained NDMA and NDEA—probable human carcinogens that were not present in their brand name counterparts or in properly manufactured generic equivalents. See Doc. No. 122, PIMC at ¶ 186–87.

Accordingly, the Court **DENIES** the Manufacturing Defendants' motion to dismiss the **strict liability-design defect claims in the PIMC** that arise under the laws of states that do NOT prohibit strict liability- design defect claims.

5.2 STRICT LIABILIY: FAILURE TO WARN CLAIMS

5.2.1 Against Manufacturing Defendants in the PIMC and MMMC

The Manufacturing Defendants contend the PIMC and MMMC inadequately allege failure to warn claims because there are no allegations that they either knew or should have known about the alleged impurity in their VCDs, that the presence of the impurity was foreseeable, or that the impurity was present in quantities sufficient to cause harm. Likewise, they request this Court to dismiss plaintiffs' failure to warn claims under those states that do not allow strict liability failure to warn claims. Plaintiffs, on the other hand, simply argue they have pled that the Manufacturing Defendants knew or should have known of the contamination and that the contamination could cause cancer. Plaintiffs do not seem to contest that some states categorically reject strict liability failure to warn claims.

We agree with the Manufacturing Defendants that some states do categorically reject strict liability failure to warn claims. Specifically, Virginia, Pennsylvania, North Carolina, Massachusetts, and Delaware do not recognize strict liability failure to warn claims. *White v. APP Pharm.*, LLC, No. CIV.A.N10C-04-061CLS, 2011 WL 2176151, at *2 (Del. Super. Ct. Apr. 7, 2011); *Com. v. Johnson Insulation*, 425 Mass. 650, 653, 682 N.E.2d 1323, 1326 (1997); *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 494 (W.D.N.C. 2017); *Evans v. Nacco Materials Handling Grp., Inc.*, 295 Va. 235, 246 (2018); *Keen v. C.R. Bard, Inc.*, No. CV 13-5361, 2020 WL 4873634, at *6 (E.D. Pa. Aug. 19, 2020) (citing *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434, 453 (2014)). Therefore, plaintiffs strict liability failure to warn claims will be dismissed with prejudice under those states.

However, given our previous conclusion that plaintiffs have adequately alleged facts from which we can infer that defendants had knowledge of the contamination, it is a foregone conclusion that plaintiffs have satisfied the knowledge requirement for their failure to warn claims. We need not

recite the litany of allegations that provided circumstantial evidence of the Manufacturing Defendants' knowledge of the contamination.

Accordingly, The Court **DENIES** the **Manufacturing Defendants' motion to dismiss the strict liability-failure to warn claims in the PIMC and the MMMC** that arise under the **laws of states that do NOT prohibit strict liability failure to warn claims.**

5.3 INNOCENT SELLER STATUTES: Strict Liability Claims for Design Defect and Failure to Warn against Pharmacy Defendants and Wholesaler Defendants

The Pharmacy Defendants argue they are protected from liability by certain states' innocent seller statutes. Specifically, they meet the requirements for dismissal under these statutes because, by plaintiffs' own allegations, the product manufacturers are identified and parties to this litigation, the pharmacies did not modify, alter, or exert control over the design, labeling, or manufacture of the product, and they did not have constructive or actual knowledge of the defect at issue. The Wholesaler Defendants join in this argument and contend they are likewise protected from liability by the innocent seller statutes of various states. Plaintiffs contend the innocent seller statutes shield the Pharmacy and Wholesaler Defendants only from liability for products liability causes of action and that many of the statutes contain exceptions which may be applicable.

According to the Wholesaler Defendants' charts appended to their Motion to Dismiss, the following states have enacted "innocent seller" statutes which immunize wholesalers, retailers, and distributors from liability for product defects if they were not actively negligent but rather were mere conduits for distribution of the product: (1) Alabama: (2) Colorado: (3) Delaware; (4) Georgia; (5) Idaho; (6) Illinois; (7) Indiana; (8) Iowa; (9) Kansas; (10) Kentucky; (11) Maryland; (12) Minnesota; (13) Mississippi; (14) Missouri; (15) Nebraska; (16) New Jersey; (17) North Carolina; (18) North Dakota; (19) Ohio; (20) Oklahoma; (21) South Dakota; (22) Tennessee; (23) Texas; (24) Washington; and (25) Wisconsin.

Wholesalers and Pharmacies leave out of their argument the numerous exceptions or prerequisites for immunity. For instance, in New Jersey a product seller must submit a statutory affidavit to either the Court or the opposing party. *Fid. & Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc.*, 936 F. Supp. 2d 441, 454 (D.N.J. 2013). In Delaware, one of several requirements for this defense to apply is that the seller had no knowledge of the defect. *In re Asbestos Litig.*, 832 A.2d 705, 713 (Del. 2003). In Georgia, a product seller may become a "manufacturer" subject to statutory liability by having input or by being actively involved in the conception, design or specification of the product. *Williams v. Tristar Prod., Inc.*, 418 F. Supp. 3d 1212, 1227 (M.D. Ga. 2019) (denying summary judgment because there was evidence the defendant was more than a mere product seller as it had staff monitoring production in China and had direct involvement with the Consumer Product Safety Commission's

investigation into consumer reports regarding pressure cookers). In Missouri, if it is "unclear that a total recovery can be had against the parties remaining in suit, it is error to apply the innocent seller statute." *Thompson v. R.J. Reynolds Tobacco Co.*, No. 4:20-CV-980 MTS, 2020 WL 5594072, at *3 (E.D. Mo. Sept. 18, 2020) (concluding defendant did not satisfy threshold requirements of section 537.762 because they offered no evidence that the manufacturer defendant was financially able to fully compensate the plaintiffs for their claims). Needless to say, the innocent seller defense invoked by the Wholesaler and Pharmacy Defendants is fact intensive and not as simple as they present it to be.

Indeed, this Court's review of the case law examining whether a product seller is entitled to immunity under a state's statute reveals that courts considering the issue overwhelmingly address the merits of this defense or immunity at the summary judgment stage of the proceedings. *Gonzalez v. Reed-Joseph Int'l Co.*, No. 4:11-CV-01094, 2013 WL 1578475, at *8 (S.D. Tex. 11 Apr. 2013) [considering the innocent seller defense in the context of a motion for summary judgment]; *Hoopes v. Deere & Co.*, 117 Idaho 386, 390, 788 P.2d 201, 205 (1990) (same); *Hicks v. CNH Am.*, LLC, No. CIV.A. 3:04-CV-366-H, 2006 WL 1382267, at *2 (W.D. Ky. May 12, 2006) (same); *Lindholm v. BMW of N. Am., LLC*, 862 F.3d 648, 653 (8th Cir. 2017) (same). This makes sense given the fact-intensive nature of the inquiry. And it is because of the fact-intensive nature of this inquiry that it is inappropriate to grant the Wholesaler and Pharmacy Defendants motions to dismiss at this stage in the proceedings.

Accordingly, the Court **DENIES** the Wholesaler Defendants' and the Pharmacy Defendants' motions to dismiss as to the **strict liability-design defect claims** in the PIMC and the MMMC. These defendants , at a later, appropriate stage of these proceedings, may raise this issue with the Court by way of a motion for summary judgment.

6.0 CONCLUSION

For the reasons stated above, the Court rules as follows on defendants' motion to dismiss in the Master Complaints on the fraud-based claims, including negligent misrepresentation, and on the strict liability claims for failure to warn and for design defect:

As for the Fraud–based Claims:

Against the Manufacturing Defendants:

The Court **DENIES** the Manufacturing Defendants' motion to dismiss the **fraud-based claims (fraudulent misrepresentation; fraudulent concealment; fraud by omission; state consumer protection statute claims that sound in fraud) as well as the negligent misrepresentation claims, in the ELMC, the PIMC, and the MMMC.**.

Against the Wholesaler Defendants and the Pharmacy Defendants:

The Court **GRANTS** the Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the **fraud-based claims (fraudulent misrepresentation; fraudulent concealment; fraud by omission; state consumer protection statute claims that sound in fraud) in the ELMC, the PIMC, and the MMMC and dismisses these claims WITHOUT PREJUDICE**.

Plaintiffs may file a motion for LEAVE TO AMEND these Master Complaints as to the fraud-based claims against the Pharmacy Defendants and the Wholesaler Defendants, according to the deadline set forth in the accompanying Order.

As for the Negligent Misrepresentation Claims:

Against the Wholesaler Defendants and the Pharmacy Defendants:

The Court **GRANTS** the Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the negligent misrepresentation claims in the **in the ELMC, the PIMC, and the MMMC and dismisses these claims WITHOUT PREJUDICE**.

Plaintiffs may file a motion for LEAVE TO AMEND these Master Complaints as to the negligent misrepresentation claims against the Pharmacy Defendants and the Wholesaler Defendants, according to the deadline set forth in the accompanying Order.

As for Strict Liability-Design Defect Claims Relating to Manufacturing Defect:

Against the Manufacturing Defendants in the PIMC

The Court **GRANTS** the Manufacturing Defendants' motion to dismiss the **strict liability-manufacturing defect claim in the PIMC that arise under the laws of Delaware, Massachusetts, North Carolina, Virginia, Indiana, and Pennsylvania** and **dismisses these claims WITH PREJUDICE.**

As for Strict Liability-Design Defect Claims NOT Relating to Manufacturing Defect:

The Court **DENIES** the Manufacturing Defendants' motion to dismiss the **strict liability-design defect claims in the PIMC** that arise under the **laws of states that do NOT prohibit strict liability- design defect claims**.

As For Strict Liability- Failure To Warn Claims in the PIMC and MMMC

Against Manufacturing Defendants

The Court **DENIES** the Manufacturing Defendants' motion to dismiss the **strict liability-failure to warn claims in the PIMC and the MMMC** that arise **under the laws of states that do NOT prohibit strict liability failure to warn claims.**

The Court **GRANTS** the Manufacturing Defendants' motion to dismiss the **strict liability-failure to warn claims in the PIMC and the MMMC** that arise **under the laws of states that PROHIBIT strict liability failure to warn claims.**

Against Wholesaler and Pharmacy Defendants

The Court **DENIES** the **Wholesaler Defendants' and the Pharmacy Defendants' motions to dismiss the strict liability-failure to warn claims in the PIMC and the MMMC.**

These defendants , at a later, appropriate stage of these proceedings, may raise this issue with the Court by way of a motion for summary judgment.

Dated: 29 January 2021

/s Robert B. Kugler
ROBERT B. KUGLER
United States District Judge